UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY
(609) 989-2040

CHAMBERS OF
TONIANNE J. BONGIOVANNI
UNITED STATES MAGISTRATE JUDGE

U.S. COURTHOUSE
402 E. STATE STREET, RM 6052
TRENTON, NJ 08608

June 9, 2009

LETTER ORDER

Re: Medeva v. Roxane
Civil Action No. 07-5165 (FLW)

Dear Counsel:

The Court is in receipt of the various correspondence from both parties in the above-referenced matter regarding outstanding discovery issues. At the outset, the Court notes that as stated by the Supreme Court in Graham v. John Deere Co. of Kansas City, 383 U.S. 1, 17-18 (1966), "[s]uch secondary considerations as commercial success, long felt but unsolved needs, failure of others, etc., might be utilized to give light to the circumstances surrounding the origin of the subject matter sought to be patented. As indicia of obviousness or nonobviousness, these inquiries may have relevancy." Further, "the commercial response to an invention is significant to determinations of obviousness, and is entitled to fair weight." Demaco Corp. v. F. Von Langsdorff Licensing Ltd., 851 F.2d 1387, 1391 (Fed. Cir. 1988). With this background and having reviewed the submissions by the parties and having conducted oral argument, the Court makes the following findings:

I. Plaintiffs' United Kingdom Asacol Formulation

A. Sales of Asacol in the United Kingdom

Roxane is seeking "discovery sufficient to show when the SmithKline formulation first became commercially available in the U.K. and the other jurisdictions cited in the prosecution history of the '170 patent." (Roxane's Letter of January 13, 2009 at 3.)

Medeva is hereby instructed to produce information outlining when the formulation first became commercially successful in the United Kingdom, Canada and Italy. Exhibit A of Roxane's January 13, 2009 submission contained a Declaration pursuant to 37 C.F.R. 1.132, dated May 6, 1994, which asserts "[o]n a global basis ASACOL has become the leading sulfapyridine-free 5-ASA product with increasing sales. In particular, it is the leading product in, *inter alia*, Canada, Italy, UK and USA." Though the Declaration contains a table listing the approximate sales since the product was first launched in 1982, it fails to provide a breakdown by country. Roxane's request is therefore granted.

B. United Kingdom Asacol Marketed After Issuance of the '170 Patent

Roxane is seeking "documents concerning *in vitro* and *in vivo* testing of the SmithKline Asacol, including comparative testing with other mesalamine products." (Id. at 4.) Roxanne contends that " the alleged commercial success of Asacol in the US has nothing to do with it purportedly being 'coated so as to release the [mesalamine] to the right side of the colon' as the '170 patent claims require.'" (Id. at 3.) Medeva is therefore instructed to produce any testing demonstrating the release of mesalamine. Those tests should include, as outlined in Roxane's May 20, 2009 letter, "(1)any pharmacokinetic studies to investigate the release and absorption of mesalamine; (2) radiographic studies to investigate the site of release within the GI tract; (3) other studies to investigate the site of release within the GI tract, including analyses of intestinal mucosa and the contents of the colon and/or rectum; (4) studies to investigate the pH of the GI track, and (5) studies to investigate transit time through the GI tract." (Roxane's Letter of May 20, 2009 at 2.) To the extent this information has been produced, Medeva shall so certify. Medeva shall likewise provide a certification indicating if any of the outlined testing/studies do not exist.

II. Comparative Testing of Asacol Against Other Products

Roxane is seeking "comparative testing of U.S. Asacol versus other controlled- or delayed-release formulations of mesalamine." (Roxane's Letter of January 13, 2009 at 4.) To the extent this is has not been resolved, Medeva is ordered to produce comparative testing of Asacol and other products regarding the release of mesalamine. Failed efforts of others is a secondary consideration of commercial success. See Intel Corp. v. U.S. Intern. Trade Com'n, 946 F.2d 821 (Fed. Cir.1991), citing In re Piasecki, 745 F.2d 1468, 1475 (Fed.Cir.1984).

III. Marketing of Asacol

Roxane is seeking "all internal memoranda, presentations and reports concerning plaintiffs' marketing of U.S., Canadian, and U.K. Asacol based on any purported advantages of its formulation." (Roxane's Letter of January 13, 2009 at 6.) The commercial success of a product "can have many causes unrelated to patentable inventiveness; for example, the commercial success of an 'invention' might be due not to the invention itself but to skillful marketing of the product embodying the invention." See Ritchie v. Vast Resources, Inc., 563 F.3d 1334, 1336 (Fed. Cir. 2009). Since Medeva represented at argument that it already produced information that was distributed to the public, Medeva is hereby instructed to conduct a search of internal material limited to the assertion and/or discussion that the product releases to the right side of the colon. Parties may confer on appropriate scientific search terms, e.g., "terminal ileum."

IT IS SO ORDERED.

s/ Tonianne J. Bongiovanni
TONIANNE J. BONGIOVANNI
United States Magistrate Judge